

SULZER MEDICA

NOV 16 1999

*K993067***Sulzer Spine-Tech**7375 Bush Lake Road
Minneapolis, MN 55439-2027**Phone** 612-832-5600
Fax 612-832-5620**510(k) Summary****A. Submitters' Information**

Date: November 15, 1999

Name/Address: Sulzer Spine-Tech
7375 Bush Lake Road
Minneapolis, Minnesota 55439

Telephone Number: (612) 830-6205
Fax Number: (612) 832-5620

Contact: Janell A. Colley
Regulatory Affairs Specialist

B. Device Information

Trade Name: Silhouette™ Spinal Fixation System

Common Name: Rod, hook, and screw spinal instrumentation

Classification: Class II, KWP, MNI, and MNH

Predicate Device: Silhouette™ Spinal Fixation System
K992276
(concurrence date October 1, 1999)

Device Description:

The Silhouette™ Spinal Fixation System is a temporary implant system used to correct spinal deformity and to facilitate the biological process of spinal fusion. This system is intended for posterior use in the thoracic, lumbar, and sacral areas of the spine. Implants in this system consist of hooks and/or screws connected to rods that are intended to be removed after solid fusion has occurred. The system includes polyaxial screws of varying diameters and lengths, fixed screws of varying diameters and lengths, rods in varying lengths, hooks in varying designs, and transverse connectors in fixed and adjustable widths. All implant components are top loading and top tightening. The implants in this system are manufactured from titanium alloy (Ti-6Al-4V) that conforms to ASTM F-136.

Intended Use:

When used as a pedicle screw fixation system in skeletally mature patients, the system is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the Silhouette™ Spinal Fixation System is indicated for use in patients:

- a) having severe spondylolisthesis (Grade 3 and 4) at the L5-S1 joint
- b) who are receiving fusions with autogenous graft only
- c) who are having the device fixed or attached to the lumbar or sacral spine, and
- d) who are having the device removed after the development of a solid fusion mass

When used as a hook and sacral screw system, the Silhouette™ Spinal Fixation System is intended for use in the treatment of degenerative disc disease (as defined by chronic back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), idiopathic scoliosis, spondylolisthesis, kyphotic or lordotic deformity of the spine, loss of stability due to tumors, spinal stenosis, vertebral fracture or dislocation, pseudoarthrosis, and previous failed spinal fusion. When used for this indication, screws of the Silhouette™ Spinal Fixation System are intended for sacral iliac attachment only. Hook and transverse connectors of the system are intended for posterior thoracic and/or lumbar use only. As a whole, the levels of use for hook and sacral screw fixation of this system are T1 to the sacrum.

C. Comparison of Required Technological Characteristics

The modified Silhouette™ Spinal Fixation System is substantially equivalent to the predicate Silhouette™ Spinal Fixation System. The table below provides a comparison of equivalency characteristics.

Characteristics	Equivalency
Intended Use	Identical
Anatomical Sites	Identical
Target Population	Identical
Sterilization	Identical
Packaging	Identical
Operating Principle	Identical
Materials	Identical
Labeling	Substantially Equivalent
Physical Characteristics (Design)	Substantially Equivalent
Performance Testing	Substantially Equivalent
Safety Characteristics	Substantially Equivalent

D. Summary of Non-Clinical Tests

The following is a summary of the testing performed on the modified Silhouette™ Spinal Fixation System:

Modification	Test Performed	Acceptance Criteria	Test Results
Addition of Adjustable Transverse Connector	Fatigue Testing of Silhouette™ Spinal Fixation System/adjustable transverse connector construct per ASTM Provisional Standard PS 5-94, <u>Test Method for Static and Dynamic Spinal Implant Assembly in a Corpectomy Model</u>	No Failures 156 N run-out load 5,000,000 cycles	Passed

E. Conclusions Drawn From Testing

Testing of the modified Silhouette™ Spinal Fixation System demonstrates that the device is substantially equivalent to the predicate Silhouette™ Spinal Fixation System and that the design modifications do not affect device safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 1999

Ms. Janell A. Colley
Regulatory Affairs Specialist
Sulzer Spine-Tech
7375 Bush Lake Road
Minneapolis, Minnesota 55439-2027

Re: K993067
Trade Name: Silhouette™ Spinal Fixation System
Regulatory Class: II
Product Codes: KWP, MNH and MNI
Dated: October 21, 1999
Received: October 22, 1999

Dear Ms. Colley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

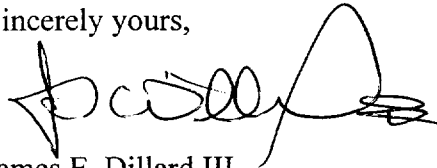
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. Janell A. Colley

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'James E. Dillard III', with a large, stylized loop at the end.

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT**510(K) Number:** K993067**Device Name:** Silhouette™ Spinal Fixation System**Indications for Use:**

When used as a pedicle screw fixation system in skeletally mature patients, the Silhouette™ Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

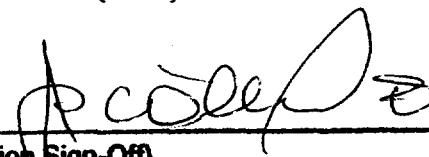
In addition, when used as a pedicle screw fixation system, the Silhouette™ Spinal Fixation System is indicated for use in patients:

- a) having severe spondylolisthesis (Grade 3 and 4) at the L5-S1 joint
- b) who are receiving fusions with autogenous graft only
- c) who are having the device fixed or attached to the lumbar or sacral spine, and
- d) who are having the device removed after the development of a solid fusion mass

When used as a hook and sacral screw system, the Silhouette™ Spinal Fixation System is intended for use in the treatment of degenerative disc disease (as defined by chronic back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), idiopathic scoliosis, spondylolisthesis, kyphotic or lordotic deformity of the spine, loss of stability due to tumors, spinal stenosis, vertebral fracture or dislocation, pseudoarthrosis, and previous failed spinal fusion. When used for this indication, screws of the Silhouette™ Spinal Fixation System are intended for sacral iliac attachment only. Hook and transverse connectors of the system are intended for posterior thoracic and/or lumbar use only. As a whole, the levels of use for hook and sacral screw fixation of this system are T1 to the sacrum.

**PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF
NEEDED**

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993067

Prescription Use 
(Per 21 CFR 801.109)

OR

Over-the-Counter-Use